DOCKET NO.: CP245
Application No.: 10/660,058
Office Action Dated: April 4, 2007

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REMARKS

Claims 1-46 are currently pending in this application. Claims 11-17 and 19 have been withdrawn from consideration. Claims 1-10, 18 and 20-44 are rejected, and claims 18, 43 and 44 are objected to. Claims 3, 5, 7-9, 18, 20-24, 27, 29, 31-33, 35-37, 41 and 42 have been amended, and claims 1, 4, 6, 10, 25, 28, 30, 34, 43 and 44 have been cancelled. Claims 45 and 46 are new Applicants submit that no new matter has been added by way of these amendments. Applicants note that the restriction requirement made of record has been made final, and hereby affirm the right to file one or more divisional applications with respect to any of the non-elected subject matter.

Applicants respectfully request reconsideration of the rejections of record in view of the foregoing amendments and the following remarks.

Claim Objections

Claims 43 and 44 are objected to on the basis that they are duplicates of claims 41 and 42, respectively. Claims 43 and 44 have been cancelled, therefore, withdrawal of the objection is respectfully requested.

Claim 18 is objected to because it refers to a "Fig. 3". In an attempt to overcome the rejection, Applicants have amended claim 18 to summarize the information contained in Figure 3, as supported by the present specification on page 7, line 27 to page 8, line 6. On this basis, withdrawal of the objection is respectfully requested.

Double Patenting

Claims 1-10, 20-22, 25-35, 43 and 44 have been rejected on the ground of non-statutory obviousness-type double patenting, as allegedly being unpatentable over claims 1-3, 30 and 31 of U.S. Patent No. 6,919,378 (B2). Claims 1-10, 20-22, 25-35, 43 and 44 have been rejected on the ground of non-statutory obviousness-type double patenting, as allegedly being unpatentable over claims 1-4, 26 and 35-39 of U.S. Patent No. 6,489,363 B2. Claims 1-10, 20-22, 25-35, 43 and 44 have been rejected on the ground of non-statutory obviousness-type double patenting, as allegedly being unpatentable over claims 6-8, 10, 11, 14 and 52-60 of co-pending Application

No. 10/155,913. Claims 1-10, 18 and 20-44 have been rejected on the ground of non-statutory obviousness-type double patenting, as allegedly being unpatentable over claims 93, 94, 97 and 98 of co-pending Application No. 10/243,557.

In view of the foregoing outstanding claim rejections made on the basis of alleged non-statutory obviousness-type double patenting, Applicants respectfully request that any determination of double patenting be deferred until prosecution on the merits has concluded, so that a more accurate determination can be made on the basis of the claims which ultimately gain allowance. On this basis, withdrawal of the rejection at this time is respectfully requested.

Claim Rejections – 35 USC § 112

Claim 36 has been rejected under 35 USC § 112 as being allegedly indefinite, on the basis that the inactive "binder" set forth in claim 36 allegedly renders the claim indefinite because it depends from claim 35, which is free of magnesium silicate or talc (which are allegedly known in the art as binders). Without conceding the correctness of the rejection, and to advance prosecution, Applicants have amended claim 36 to exclude a binder. Withdrawal of the rejection is respectfully requested.

Claim Rejections – 35 USC § 102

Claims 1, 4, 6, 18, 21, 25, 28, 30 and 35 have been rejected under 35 USC 102(b) as allegedly anticipated by US Patent No. 5,401,774 (hereinafter "Laurent"). Applicants submit, in view of the present amendments, that the rejection is moot and respectfully request withdrawal of the rejection.

Claim Rejections – 35 USC § 103

Claims 2, 3, 5, 7-10, 20, 22-24, 26, 27, 29, 31-34 and 38-44 have been rejected under 35 USC § 103(a) as allegedly unpatentable on the basis of obviousness in light of US Patent No. 5,401,774 (hereinafter 'Laurent"). Applicants respectfully traverse.

To establish *prima facie* obviousness, the Patent Office must provide objective evidence that the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, contains some suggestion or incentive that would have motivated those of

ordinary skill in the art to modify a reference or to combine references. *In re Lee*, 61 U.S.P.Q.2d 1430, 1433 (Fed. Cir. 2002); *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir.1998).

Applicants respectfully submit that there is no suggestion or incentive for one skilled in the art to modify the weight-based dosing regime described in Laurent so as to employ the flat-dosing regime set forth in the present application. Of the three examples described in Laurent, only Example 1 employs a single dose of 400 mg of modafinil; Examples 2 and 3 rely on weight-based doses of 10 mg/kg and 5 mg/kg of modafinil, respectively (col. 1 ln. 46 to col. 4 ln. 36). Favorable and effective results were obtained in both of the examples where modafinil was administered according to a weight-based dosing regimen. Example 2 employed forty human subjects, all of whom received a dosage of modafinil based on individual weight. Likewise, in Example 3, six feline test subjects received a dosage of modafinil according to individual weight. Applicants submit that there is no teaching in Laurent which advises or suggests the particular desirability of flat-dosing of modafinil, since favorable results were achieved in all three examples. Moreover, Laurent suggests that "the administered doses may be from 1 mg/kg to 100 mg/kg and **preferably** from 5 to 100 mg/kg." (col. 1, ln. 38 to ln. 40) (emphasis added). Therefore, on the basis of the teachings and guidance provided by Laurent as a whole, Applicants submit that one of skill in the art would not be motivated to modify Laurent to arrive at the discrete range of dosage units set forth in the present application. On the basis of the foregoing, Applicants respectfully request that the outstanding rejection made pursuant to 35 USC § 103(a) be withdrawn.

Claims 35, 36 and 37 are rejected under 35 USC § 103(a) as allegedly unpatentable in view of Laurent (as applied to claims 2, 3, 5, 7-10, 20, 22-24, 26, 27, 29, 31-34 and 38-44) and further in view of Lawyer et al (US 2003/0171439A1) (hereinafter "Lawyer").

Applicants submit that the present invention is not obvious in light of Laurent for the reasons of record stated above. Applicants further submit that the teachings of Lawyer fail to cure the deficiencies of Laurent, and that the two references, taken together as a whole, do not render the presently claimed invention obvious. On this basis, Applicants respectfully request that the outstanding rejection made pursuant to 35 USC § 103(a) be withdrawn.

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Conclusion

In view of the foregoing, Applicants submit that the pending claims, as amended, are in allowable form. In the event that the Examiner finds any remaining impediment to the allowance of this application, which could be clarified by a telephonic interview, or which is susceptible to being overcome by means of an Examiner's Amendment, the Examiner is respectfully requested to initiate the same with the undersigned attorney.

Respectfully submitted,

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